

DOCKET NO.: 243129US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF :  
MARCO PINNA ET AL : EXAMINER: FERNANDEZ, SUSAN  
SERIAL NO.: 10/673,178 :  
FILED: SEPTEMBER 30, 2003 : GROUP ART UNIT: 1651  
FOR: QUICK WATER-DISSOLVING :  
FILM CONTAINING COSMETIC,  
AROMATIC, PHARMACEUTICAL OR  
FOOD SUBSTANCES

DECLARATION UNDER 37 C.F.R. §1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

I, Mirco CHIODERO, hereby declare:

1. I am a graduate of the Università degli Studi di Milano (University of Milan, Italy), and I received my Master of Science in Chemistry degree in the year 1972.
2. I am qualified as professional chemist and
  - a. I am a member of the Regional Order of Chemists, with registration No. 2537 of the year 1984;
  - b. I am a member of the SCI (Società Chimica Italiana: Italian Chemical Society), with registration No. 14555;
  - c. Since 1974, I have been employed by the company ICMA S.r.l. My present position is manager of R & D.

3. I have previously consulted with the assignee of the above-captioned patent application (BIOFARMITALIA S.p.A. of Milan Italy) relating to this application and in other matters, and have received compensation for such consultation.

4. I am not employed by the assignee of the above-captioned patent application and have not been employed by the assignee in the past.

5. I am being compensated for my time in preparing the present Declaration and for providing my opinion with respect to the above-captioned patent application and the references discussed herein. My compensation does not depend on the outcome of the prosecution of the above-captioned patent application.

6. I have reviewed and understand the contents of the above-captioned patent application.

7. I have reviewed and understand the contents of U.S. Patent No. 6,419,903 to Xu et al. ("Xu"), U.S. Patent No. 4,345,032 to Hata ("Hata") and U.S. Patent No. 5,206,026 to Sharik ("Sharik"), which I have been informed were cited by the Examiner as prior art against the claims of the above-captioned patent application.

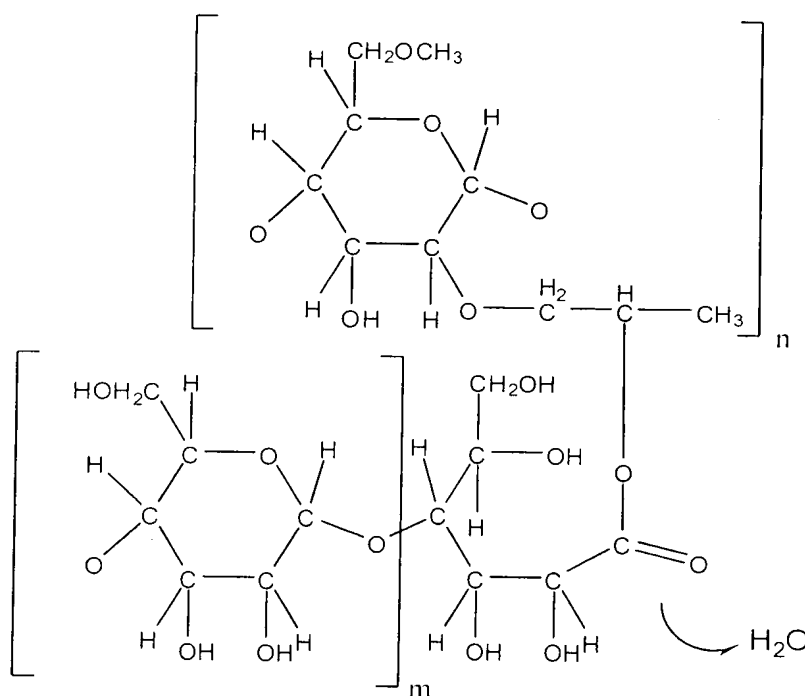
8. One or more of the claims of the above-captioned patent application is directed to a composition that includes an oxidized starch and a cellulose. Such claims require that the oxidized starch and the cellulose are chemically bonded to one another.

9. It is my opinion that one of ordinary skill in the art would readily recognize that under the conditions of the Examples disclosed in the specification of the above-captioned patent application that oxidized starch and cellulose inherently form a chemical bond.

10. For example, Example 1, described at pages 5-7 of the specification of the above-captioned patent application, involves heating a mixture that includes oxidized starch and hydroxypropylmethyl cellulose (i.e., a cellulose). Oxidized starch has acidic carboxyl

groups (i.e., groups of formula  $\text{-COOH}$ ). Cellulose has hydroxyl groups (i.e., groups of formula  $\text{-OH}$ ).

11. Under the conditions described in Example 1 of the above-captioned patent application (i.e., heating a mixture of oxidized starch and hydroxypropylmethyl cellulose at a temperature of  $90^\circ\text{C}$ ), a transesterification (condensation) reaction takes place (with consequent formation and loss of water) between the hydroxyl groups ( $\text{-OH}$ ) of the cellulose and the carboxyl groups ( $\text{-COOH}$ ) of the oxidized starch. A diagram showing how an oxidized starch and a cellulose are chemically bonded to one another by the transesterification reaction is set forth below, the formation and loss of water being represented by the symbol  $\text{H}_2\text{O}$ .



12. An esterification reaction taking place between oxidized starch and cellulose (e.g., hydroxypropylmethyl cellulose) forms a strong chemical bond between the oxidized starch and the cellulose. Such a reaction is common knowledge in the field of the condensation of macromolecules.

13. An esterification reaction inherently takes place between the oxidized starch and the hydroxypropylmethyl cellulose under the conditions described in Example 1 of the above-captioned patent application.

14. Accordingly, the specification of the above-captioned patent application inherently discloses, in Example 1, a composition containing an oxidized starch and a cellulose chemically bonded to one another (e.g., through an ester bond).

15. It is my understanding that the Examiner is of the belief that Example 1 of Xu describes a composition containing starch and cellulose that are bound in stable form.

16. At column 5, lines 1 to 3, Xu describes a mixture of pregelatinized starch and a cellulose. A pregelatinized starch is different from an oxidized starch. Pregelatinized starch is a starch that has been heated in the presence of water to allow the hydrogen bonding sites of the starch to engage more water. This process physically changes the form of the starch but does not oxidize the starch. Pregelatinized starch and oxidized starch are chemically different and have different reactivity with hydroxyl groups (e.g., in cellulose).

17. The pregelatinized starch described in Example 1 of Xu is not oxidized starch and does not have the carboxyl groups (-COOH) necessary to undergo an esterification reaction with cellulose. Therefore, Example 1 of Xu does not disclose a composition that includes an oxidized starch chemically bonded to a cellulose, e.g., through an ester bond.

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18. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; these statements were made with the knowledge that willful false statements are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing therefrom.

Date: January 07, 2008 Mirco Chiodero  
Mirco CHIODERO